IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of: **SAITO, Shuji et al.**

Group Art Unit:**1648**

Serial No.: **10/059,152**

Examiner: **Ali Reza Salimi**

Filed: **January 31, 2002**

P.T.O. Confirmation No.: 5985

For: **RECOMBINANT HERPESVIRUS OF TURKEYS AND USE THEREOF**

SUBMISSION OF APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, Va 22313-1450

October 29, 2003

Sir:

Submitted herewith are an original and two copies of an Appeal Brief in the above-identified U.S. patent application.

Also enclosed is a check in the amount of **$330.00** to cover the cost of filing this Appeal Brief. In the event that any additional fees are due with respect to this paper, please charge Deposit Account No. 01-2340. This paper is filed in triplicate.

Respectfully submitted,

ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP

Daniel A. Geselowitz, Ph.D.
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DAG/plb
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PATENT TRADEMARK OFFICE

Enclosures: Duplicate of this paper; Appeal Brief and two copies; and check for **$330.00**
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COPY

CARD NO: 06196

U.S. Patent Application Docket No: 020058
Serial No: 10/059,152 Filed: 01/31/02
Patent Number: Issued:
Applicant(s): SAITO, Shuji et al.

Papers filed herewith on: 10/29/03

Fees: $ 330.00

Other: Sub. of Appeal Brief cover sheet; Appeal Brief (3)

COMMISSIONER OF PATENTS

Receipt is hereby acknowledged of the papers filed as indicated in connection with the above-identified case.

DAG/PLB

AF/1648 IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of: **SAITO, Shuji et al.**

Group Art Unit:**1648**

Serial No.: **10/059,152**

Examiner: **Ali Reza Salimi**

Filed: **January 31, 2002**

P.T.O. Confirmation No.: 5985

For: **RECOMBINANT HERPESVIRUS OF TURKEYS AND USE THEREOF**

COMMUNICATION TO THE EXAMINER

Commissioner for Patents
P.O. Box 1450
Alexandria, Va 22313-1450

August 12, 2004

Sir:

Applicants respectfully request consideration of the Brief on Appeal along with the Submission of Appeal Brief and postcard which were filed on October 29, 2003 with the United States Patent and Trademark Office. These papers were received by the Patent Office as evidenced by the copy of the stamped postcard. A copy of the Brief on Appeal and associated papers are enclosed herewith.

The Examiner's assistance in addressing this matter is greatly appreciated.

No fees are believed to be due. However, the Commissioner is authorized to charge any additional fees which may be required for consideration of this paper to Deposit Account No. 01-2340.

Respectfully submitted,

ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP

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PATENT TRADEMARK OFFICE

Enclosures: 1) Copy of Brief on Appeal filed on October 29, 2003;
2) Submission of Appeal Brief filed on October 29, 2003; and
3) Stamped Postcard dated October 29, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

APPEAL BRIEF FOR THE APPELLANTS

Ex parte Shuji SAITOH et al. (applicant)

Serial Number: **10/059,152**

Filed: **January 31, 2002**

Appeal No. :

COPY

Group Art Unit: **1648**

Examiner: **Ali Reza Salimi**

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PATENT TRADEMARK OFFICE

Date: October 29, 2003

Atty. Docket No. **020058**
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THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No:

In re the Application of: **SAITO, Shuji et al.**

Group Art Unit: **1648**

Serial No.: **10/059,152**

Examiner: **Ali Reza Salimi**

Filed: **January 31, 2002**

P.T.O. Confirmation No.: 5985

For: **RECOMBINANT HERPESVIRUS OF TURKEYS AND USE THEREOF**

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

October 29, 2003

Sir:

I. REAL PARTY IN INTEREST

The real party in interest is Zeon Corporation of Tokyo, Japan, as evidenced by the assignment recorded May 13, 2002, Reel 01286, Frame 0606.

II. RELATED APPEALS AND INTERFERENCES

Appellant knows of no other appeal or interference which will directly affect or be directly affected by or have a bearing on the Board's decision on this appeal.

III. STATUS OF CLAIMS

Claims 1-6 are pending in this application. No claim has been canceled in the prosecution of this application. The rejection of claims 1-6 is under appeal.

IV. STATUS OF AMENDMENTS

No amendment has been filed subsequent to the final Office action dated June 17, 2003.

V. SUMMARY OF THE INVENTION

Claim 1 recites:

> A recombinant herpesvirus of turkeys harboring an F protein gene of Newcastle disease virus under the control of a promoter of which sequence is shown in SEQ No. 1;
>
> wherein said recombinant heresvirus of turkeys does not comprise an HN gene.

The invention as recited in **claim 1** is a **recombinant herpesvirus of turkeys**. In the discussion of the related art on page 3 of the specification, the use of recombinant herpesvirus of turkeys (rHVT) as vaccines is discussed. The specification also indicates on page 6, second paragraph, that any herpesvirus of turkeys that is non-pathogenic to chickens may be used in making the present invention, indicating that the term "herpesvirus of turkeys" is defined in the art. Several specific known strains of herpesvirus of turkeys are listed as being suitable for the backbone virus of the recombinant virus.

The recombinant herpesvirus of the invention **harbors an F protein gene of Newcastle disease virus**. That is, the F protein gene of Newcastle virus is present in the gene sequence of the recombinant herpesvirus of the invention. Newcastle disease virus is discussed at length on pages 1-2 of the specification, indicating that this disease is defined in the art. The F protein gene is

discussed on pages 3-4 of the specification, with respect to the related art. The specification indicates on page 5, second paragraph, that any gene from NDV encoding the NDV F protein is appropriate for the present invention.

Claim 1 further recites that the F protein gene of Newcastle disease virus is **under the control of a promoter of which sequence is shown in SEQ No. 1**. The sequence of SEQ No. 1, given in the specification on page 5 and in the sequence listing, is designated the Pec promoter, as discussed in the bottom paragraph of page 5 to page 6.

Claim 1 further recites that **said recombinant herpesvirus of turkeys does not comprise an HN gene.** Recombinant herpesviruses of turkeys of the related art that include the HN gene are discussed in the specification in the second full paragraph on page 3 through the first paragraph on page 4. The specification discusses related art recombinant herpesvirus of turkeys having the F gene but not the HN on page 4, lines 5-7, but indicates that this related art did not induce desirable immunity as a vaccine. The specification indicates on page 4, lines 2-5, that there are problems associated with HN protein in recombinant HVTs, and that a goal of the present invention is a recombinant virus expressing F gene. That is, the description of the construction of the rHVT of the invention is disclosed on pages 7-8 of the specification, and it can be seen that HN is not inserted into the recombinant herpesviruses of the present invention.

Claim 2 depends from claim 1 and further recites that "**the promoter and F protein gene are inserted into a noncoding, inter-ORF region of the backbone virus genome**." This limitation defines the location of the promoter and the F protein gene relative to the sequence of the herpesvirus of turkeys which is used to make the recombinant herpesvirus of the invention. The inter-ORF region is discussed in detail in the last paragraph on page 6 through the first paragraph of page 7 of the specification. The inter-ORF region between UL44 and UL46 is mentioned as being most suitable. In the discussion of the related art in the second full paragraph on page 3 of the specification, the use of the intergenic region between UL44 and 45 or between UL45 and 46 for insertion of F and HN proteins is discussed.

Claim 3 depends from claim 2 and further limits the noncoding region to **that located between UL45 and UL46 of the herpesvirus genome**. As noted above, this region is discussed in the related art.

Claim 4 recites **a method of inducing protective immunity in an avian host against avian herpesvirus and Newcastle disease virus**. As noted above, Newcastle disease virus and avian herpesvirus are discussed in several places in the specification. Protective immunity is discussed generally in the specification with regard to the prior art on pages 2-4. Protective immunity against Newcastle disease virus is assayed by the efficacy test disclosed in Examples 5 and 6 on pages 25

and 26 of the specification, which involves challenging chickens with a standard strain of NDV and inspecting for onset of disease or mortality.

The method of claim 4 **comprises inoculating the avian host with the recombinant herpesvirus of turkeys as in claim 1, 2 or 3**. Inoculation of a chicken as host is described, for example, in Examples 5 and 6, as discussed above.

Claim 5 depends from claim 4 and recites that **a recombinant herpesvirus of turkeys is administered to the avian host by subcutaneous or in ovo route**. These are well known routes of administration. Subcutaneous inoculation may be seen in Example 5 and in ovo inoculation may be seen in Example 6 of the specification.

Claim 6 recites **a poultry vaccine comprising a recombinant herpesvirus of turkeys as in claim 1, 2 or 3**. Poultry vaccines in general are known in the art, as discussed on pages 1-4 of the specification.

VI. ISSUES

A. Whether claims 1-6 are unpatentable under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention.

B. Whether claims 1-6 are unpatentable under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the claims.

VII. GROUPING OF THE CLAIMS

For purposes of the appeal, the claims are grouped as follows:

Group I: Claims 1 and 2

Group II: Claims 3 and 6

Group IV: Claims 4 and 5.

VIII. ARGUMENTS

Issue A. Whether claims 1-6 are unpatentable under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention.

Errors in the rejection and how the claims particularly point out and distinctly claim the subject matter which applicant regards as the invention. (37CFR 1.192(c)(8)(ii)).

In the final Office action, the Examiner cites the reasons of record of the first Office action, dated February 27, 2003, for the rejection of claims 1-6. The rejections of the claims are discussed below with regard to the rejection in the first Office action and the Examiner's response in the final Office action to Applicants' traversal of that rejection.

Claim Group I (Claims 1 and 2)

Claim 1. In the first Office action of February 27, 2003, the Examiner states that :

> "Claim 1 is vague and indefinite, the intended region or regions where the F protein maybe [sic] inserted is not defined. Is it the intent to insert the F protein in essential regions of herpesvirus of turkeys? This affects the dependent claims."

Claim 1 was amended in the Amendment of May 23, 2003, but this amendment was not in regard to this rejection, and the rejection was traversed in the Amendment. Therefore, the reasons for rejection of claim 1 in the final Office action of June 17, 2003, are the same as in the Office action of February 27, 2003.

Applicants submit that this rejection of claim 1 has the following error. In the rejection, the Examiner is **not** pointing out any indefiniteness in the claim. The Examiner states that "the intended region or regions where the F protein may be inserted is not defined." However, the claim **does not limit** the F protein to any particular region of the recombinant virus, except to the extent that it must be under the control of the recited promoter. (Applicants note that claim 2 further limits claim 1 by limiting the location of insertion of the F protein gene.) The region for insertion of the F gene is also well described on pages 6-7 of the specification. The Examiner is, in effect, requesting a **narrowing** of the claim. However, this is not a matter of the **definition** of the invention of claim 1, but rather a matter of the scope of the claim.

That is, the Examiner apparently thinks that claim 1 is too broad by not further limiting the region where the F protein gene is harbored. Applicants submit that this is an error in the rejection.

MPEP 2173.04 discusses the principle that "**Breadth of a claim is not to be equated with indefiniteness**", citing *In re Miller*, 441 F.2d 689, USPQ 597 (CCPA 1971).

In the final Office action, in responding to Applicants' arguments traversing the rejection, the Examiner states:

> "Conterrey [sic] to applicants' assertion the specific region for the insertion of a heterologous gene is **extremely important** since the **viability** of the virus depends on the insertion region. The claim should clearly state where the foreign gene is to be placed." (emphasis added)

Applicants respectfully submit that this reasoning perpetuates the error in the rejection.

Applicants note first of all that the Examiner refers to what is "**extremely important**" for the claim, which is a subjective statement apparently **not related to indefiniteness**.

Secondly, the Examiner refers to "**viability**," a term **not recited in the claims or the specification**, and a fairly vague term in itself. The Examiner may be referring to the fact that the claim recites a "recombinant herpesvirus," since the preparation of recombinant viruses usually involves some sort of culturing of the virus. Applicants note that the specification discusses recombinant herpesviruses in detail, as discussed in the Summary section above, and on page 7, bottom paragraph, states: "For the present invention, any known method of generating the recombinant avian herpesvirus is applicable." That is, so long as the F protein gene is in a recombinant herpesvirus and is under the control of the promoter of SEQ No. 1, the location of the F protein gene **is defined** in claim 1.

Claim 2. In the Office action of February 27, 2003, the Examiner states:

> "Claim 2 is vague and indefinite for recitation of 'non-coding, interORF [sic] region' the intended metes and bounds of the said region is not defined. Is the UL55 region intended?"

Applicants submit that the "noncoding, inter-ORF region" is defined by the specification. As discussed in the Summary section above, the inter-ORF region is discussed in detail in the last paragraph on page 6 through the first paragraph of page 7 of the specification. This is a well known term in the art. The general reasons for insertion into an inter-ORF region are also known in the art. Claim 3 further limits the noncoding region to the region between UL45 and UL46. It is therefore also clear by the principle of claim differentiation that the noncoding, inter-ORF region of claim 2 encompasses more than the region between UL45 and UL46.

In the final Office action (page 3, line 11), the Examiner addresses Applicant's traversal of the rejection, stating :

> "Regarding claim 2, the specification on page 6 refers to UL43, US2, and only inter-ORF region between UL44 and UL46. The UL43, and US2 are not inter-ORF regions, hence, the intended metes and bounds of the region is not defined. In addition, the limitations from the specification is not read into the claim."

Applicants respectfully submit that this argument by the Examiner propagates the error in the rejection. Here, the Examiner appears to infer from page 6 of the specification that UL43 and US2 are not in the inter-ORF region. However, if these are not in the inter-ORF regions, then they fall outside the metes and bounds of the region in claim 2. There is no indefiniteness in this regard.

Applicants are uncertain what is meant by "the limitations from the specification [are] not read into the claim." Here, the Examiner appears to cite two examples of regions outside the inter-

ORF regions, and then to apply these examples to claim 2, which **requires** the inter-ORF region. Examples outside of the inter-ORF regions are, however, clearly **not within the scope of** claim 2. Such examples would fall within the bounds of broader claim 1. Although Applicants do not fully understand the Examiner's reasoning regarding page 6 of the present specification and claim 2, Applicants submit that this reasoning is in error an does not indicate indefiniteness in claim 2.

Claim Group II (Claims 3 and 6)

In the first Office action of February 27, 2003, and in the final Office action of June 17, 2003, the Examiner does not appear to address any remarks to claims 3 and 6, and these claims are apparently rejected only on the basis of their dependency from claim 1 or 2. Applicants have argued above that claims 1 and 2 are definite and particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants also submit that the additional limitations in claims 3 and 6 are well defined in view of the disclosure in the specification as discussed above.

Claim Group III (Claims 4 and 5)

a) In the first Office action, the Examiner stated:

"Claim 4 is rejected ... as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP §2172.01. The omitted elements are: the antigens of "avian herpesvirus" wherein the protective immunity is induced against is/are not defined. This [affects] claim 5."

Applicants submit that claim 4 does not omit essential elements. Claim 4 recites a method comprising one recited step: "inoculating the avian host with the recombinant herpesvirus of turkeys as in claim 1, 2, or 3." Applicants submit that this step distinctly claims the method, and no element is missing in this recitation.

Moreover, Applicants respectfully submit that the Examiner is in error in referring to "the antigens of 'avian herpesvirus' wherein the protective immunity is induced". First of all, the Examiner refers to the preamble, "A method of inducing protective immunity in an avian host against avian herpesvirus and Newcastle disease virus", which states the **utility** of the recited method, but is not in itself limiting.

Secondly, the present specification defines what is meant by protective immunity, as discussed above in the Summary of the Invention section. Protective immunity is discussed generally in the specification with regard to the prior art on pages 2-4. Protective immunity against Newcastle disease virus is assayed by the efficacy test disclosed in Examples 5 and 6 on pages 25 and 26 of the specification, which involves challenging chickens with a standard strain of NDV and inspecting for onset of disease or mortality. The term "protective immunity" is well known in the art and this aspect of the claim is defined.

The Examiner may be referring to the fact that protective immunity can be inferred from an antibody titer, as discussed in Example 8 on pages 28-29. However, this is simply a method of detecting whether protective immunity has been induced without the need for actual challenge with the disease. The antibody titer does not in itself define "protective immunity."

In response to Applicants arguments traversing this rejection, in the Final Office action (page 3, line 15), the Examiner states:

> "As for claim 4, applicants are requested to read their own claim. The claim specifically states that 'protective immunity' is induced in an avian host against 'avian herpesvirus and Newcastle disease virus', the protective response in induced by the host is induced by the host against the antigen [emphasis in original], how else the response is directed? Since, the specific antigens are not recited the claim is indeed indefinite."

Applicants respectfully submit that this response by the Examiner maintains the error of the original rejection. The Examiner is discussing "antigens" as the **mechanism** by which the protective immunity is induced. Although the specification does discuss proteins expressed by the recombinant herpesvirus, implying that these are related to the biological mechanism of action, Applicants submit that **the biological mechanism by which the protective immunity is induced is not relevant at all to the scope of claim 4.** In particular, the mechanism clearly has nothing to do with the issue of definiteness of claim 4. Claim 4 recites that the herpesvirus is inoculated into the host, and that the purpose of this inoculation is to induce protective immunity. Claim 4 does not recite any mechanism of action.

With regard to Applicants remarks on mechanism of action made in the Amendment of May 23, 2003, the Examiner further states:

> "Still further, the Office did not ask for mechanism of action under this statute, how ever, the claim is reciting 'protective immunity' which is an action [that] is [supposed] to be [performed] by the [method], and one should be [appraised] of what the [elements] are in the [method which] are [supposed] to induce 'protective immunity', and that is what the Office asked."

Again, Applicants respectfully submit that the Examiner is inappropriately raising the issue of mechanism of action, which is irrelevant to this rejection. The "antigens" do not represent missing elements in the claims, and claims 4 and 5 are definite without the recitation of "antigens".

b) In the first Office action, the Examiner stated:

> "Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. MPEP §2172.01. The omitted steps are: when to apply the vaccine, how to apply, the effective amount, etc.. This [affects] claim 5."

Applicants respectfully submit that the Examiner's statement represents an error in the rejection. What the Examiner refers to as omitted steps, such as "when to apply the vaccine", are in fact not additional steps at all, but rather potential limitations on the recited step of "inoculating the avian host ..." in claim 4. (In fact, Applicants note that claim 5 does further limit how the inoculation is performed.)

That is, the Examiner is not pointing out omitted steps, but rather is **suggesting additional claim limitations**, that is, suggesting that the claim be narrowed. Applicants submit that the Examiner's remarks give no indication of indefiniteness in claim 4 and again note MPEP 2173.04, discussing the principle that "**Breadth of a claim is not to be equated with indefiniteness.**"

Applicants argue that claim 4 distinctly claims the subject matter of the invention. Inoculation of viruses into chickens is well known in the art and is described in the specification, and this recitation of the claim is completely definite.

The Examiner apparently did not respond in the final Office action to Applicants arguments traversing this portion of the rejection.

c) In the first Office action, the Examiner stated:

> "Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP §2172.01. The omitted structural cooperative relationships are: the relationship of Newcastle with other "avian herpesvirus" antigens is/are not defined. This [affects] claim 5."

Applicants respectfully submit that these remarks represent an error in the rejection.

First of all, claim 4 is a method claim reciting a method comprising one step. This is not a recitation of a device involving multiple elements which are structurally related.

Secondly, the Examiner refers to the relationship of Newcastle with other "avian herpesvirus" antigens, although it is unclear if he is referring to Newcastle disease here. However, as noted above, "antigens" are not even recited in the claims, and as argued above, "antigens" do not represent missing elements in the claims. Applicants respectfully submit that there is no relationship to define between the unrecited "antigens" and Newcastle disease.

The Examiner apparently did not respond in the final Office action to Applicant's arguments traversing this portion of the rejection.

Applicants therefore assert that claims 1-6 particularly point out and distinctly claim the subject matter which the applicant regards as the invention, and therefore request withdrawal of the rejection of claim groups I, II and III under 35 U.S.C. 112, second paragraph.

Issue B. Whether claims 1-6 are unpatentable under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the claims.

Errors in the rejection and how the first paragraph of 35 U.S.C. 112 is complied with, including how the specification and drawings enable any person skilled in the art to make and use the subject matter defined by each of the rejected claims. (37CFR 1.192(c)(8)(i)(B)).

In the final Office action, the Examiner cites the reasons of record of the first Office action, dated February 27, 2003, for the rejection of claims 1-6. The rejections of the claims are discussed below with regard to the rejection in the first Office action and the Examiner's response in the final Office action to Applicants' traversal of that rejection.

Claim Group I (Claims 1 and 2)

Claim 1. In the first Office action of February 27, 2003, the Examiner states that:

> "Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for turkey herpesvirus (HVT) having promoter identified as SEQ ID NO: 1 being capable of expressing F protein of Newcastle disease virus (NDV) being inserted into a region between UL45 and UL46 of HVT capable of inducing protective response against Newcastle disease virus, does not reasonably provide enablement for (1) insertion of F gene in all regions of HVT in general, or "inter-Orf region" in particular (2)

> method of polyvalent vaccine wherein Newcastle disease virus as well as any and all antigens of avian herpesvirus are to induce protective response.

The Examiner goes on to state that "this field is considered to be highly unpredictable" and to imply that undue experimentation would be required to make and use the invention.

In traversing this rejection, Applicants assert that the specification does teach one of skill in the art how to make and use the invention. In particular, the Examiner refers to the location of the F protein of Newcastle virus in claim 1, which limits the location only in so far as the F protein gene is under the control of the promoter of SEQ NO. 1.

Applicants submit that the specification clearly indicates on page 7 that: "For the present invention, any known method of generating the recombinant avian herpesvirus is applicable." Applicants argue that it is an error in the rejection to infer that obtaining a recombinant of claim 1 would require "undue experimentation." Applicants submit that one of skill in the art, at the time of filing of the present application, could insert the promoter and the F protein gene at **any** of many locations in a backbone HVT virus, as described on pages 6-7 of the specification (Region for gene insertion). One of skill in the art would then use conventional procedures to obtain recombinants, and to screen for recombinants in which the F protein gene was under control of the promoter. These procedures are standard in the art of obtaining recombinants and **do not represent undue experimentation**. Upon completion of these procedures, one of skill in the art would have obtained a recombinant herpesvirus meeting the limitations of claim 1. Therefore, one of skill in the art could make the recombinant of claim 1.

In traversing the rejection in the Amendment dated May 23, 2003, Applicants also responded to the Examiner's comments regarding "unpredictability". The Examiner remarked that "[Applicants'] own disclosure is used as evidence of unpredictability in the field, see page 3 of the specification." In the Amendment (page 6, last paragraph), Applicants noted that the specification never uses the term "unpredictability" and that the Examiner apparently refers to the discussion of problems in the **related art** for vaccines having the F protein of NDV. For example, page 4, lines 6-8, indicate that "rHVT having only F gene of NDV didn't induce desirable immunity in chickens as indicated by Morgan et al." This, however, refers to **Morgan et al.'s recombinant virus**, which is not consistent with the recitation of claim 1. Moreover, Applicants submit that Morgan **has enabled** the vaccine disclosed in the reference and there is **no unpredictability issue** with regard to making or using Morgan's invention. The specification is merely pointing out that Morgan's invention does not have certain desirable characteristics that the present invention will provide. The Examiner's comments on unpredictability therefore represent another error in the rejection.

Applicants note that the further remarks starting on page 4, line 11, of the first Office action do not appear to refer to claim 1.

In the final Office action, the Examiner responds to Applicants' traversal of the rejection. The Examiner reiterates his arguments regarding unpredictability starting on page 5, line 1. In particular, the Examiner states on page 5, lines 7-9:

> "The **only reason applicants have observed the results** is because of the insertion of F gene between UL44 and 45 as taught by Saitoh et al. and because of the promoter defined

> by SEQ ID NO: 1. However, the scope of the claims are not reflective within the scope of teaching provided in the specification." (emphasis added)

In response, Applicants submit that the Examiner is improperly summarizing Applicants' invention. The Examiner is apparently referring to the working example of Example 2 of the specification, in which the PecF is inserted between UL45 and 46 (not between UL44 and 45). However, **claim 1 is not limited to this working example**. Applicants have clearly indicated that methods known in the art can generate recombinants with insertion in any of many locations in the backbone HVT. The method for determining those locations, as described on pages 6-7 of the specification (Region for gene insertion), can be readily carried out by one of skill in the art. Therefore, insertion into any location according by means of the method given in the specification is enabled.

Applicants respectfully submit that it is an error in the Examiner's reasoning to infer anything about why Applicants have observed particular results. In the Examiner's remarks, it is unclear which results are being referred to, but Applicants submit that these remarks do not indicate in any way that the invention of claim 1 is not enabled.

Applicants also note the Examiner's comment on page 5, lines 14-17, of the final Office action:

> "Absent teaching undue experimentation would be required of one of ordinary skill in the art to enable the claimed invention. Applicants do not provide argument for these issues raised and **simply dismiss it** as routine in the art." (emphasis added)

In response, Applicants believe that they did not "simply dismiss" the Examiner's arguments. Applicants believe that they clearly showed how the specification and the general knowledge in the art enable one to practice the invention of claim 1. Applicants respectfully submit that the Examiner has not even detailed the nature of the "undue experimentation" that he states must be performed to practice the invention as recited in the claims. Without a statement of what experiments the Examiner is referring to, it is not clear how the Examiner can assess the quantity of experimentation or conclude that any experimentation would be **undue**.

Finally, on page 5, line 20, the Examiner states:

> "If the vector is not able to express the gene, then it's useless, and it's important to know where the gene is inserted ...."

In response, Applicants note that if the recombinant herpesvirus does not express the F protein gene, then the F protein gene cannot be considered to be "under the control of the promoter". **A non-expressive HVT would not fall within the scope of claim 1.** The present specification clearly teaches how to test for gene expression (Example 4 Verification of the inserted gene expression by rHVT/NDV, page 24 of the specification).

Claim Group II (Claims 3 and 6)

Claim 3. Applicants note that some of the Examiner's arguments in the rejection, as discussed above for claim 1, do not appear to apply to claim 3. In particular, the Examiner states that the specification **is enabling** for F protein of NDV inserted between UL45 and UL46 of HVT, on

page 3, lines 11-15 of the first Office action. However, this is what is recited in claim 3. Applicants therefore believe that the Examiner has effectively stated that claim 3 is enabled by the specification in this regard. Claim 3 depends from claim 1, and Applicants arguments for the other issues of enablement in regard to claim 1, given above, also apply to claim 3.

Claim 6. In the first Office action and the final Office action, the Examiner does not appear to specifically address claim 6. Applicants have argued above that claims 1, 2 and 3 are fully enabled by the specification, and applicants submit that the additional limitations of claim 6 are enabled as well.

Claim Group III (Claims 4 and 5)

In the first Office action of February 27, 2003, the Examiner did not clearly indicate which remarks were directed to claims 4 and 5. However, it is Applicants' understanding that the remarks beginning on page 4, line 11, regarding a "polyvalent vaccine", cannot refer to claims 1-3, which do not recite a vaccine. Applicants assume that these remarks are made regarding claims 4-5, as claim 4 recites a "method of inducing protective immunity ... against avian herpesvirus and Newcastle disease virus." Applicants note that the term "polyvalent vaccine" does not occur in the claims. The Examiner presumably refers to the recitation in the preamble of protective immunity against avian herpesvirus **and** Newcastle disease virus.

In the first Office action, on page 4, line 11, the Examiner states: "Moreover there is no teaching presented for a method of polyvalent vaccine ..."

Applicants respectfully argue that this is an error in the rejection. As noted, Applicants do not use the term "polyvalent vaccine," but Applicants have fully enabled the method of claim 4. Applicants have shown how to make the recombinant herpesvirus of claims 1, 2 and 3, as discussed above. Moreover, Applicants have taught how to inoculate it into an avian host (and inoculation as a technique is already well known in the art). Therefore, the method, as recited, is enabled. Applicants also have provided a utility for this method, that of providing protective immunity. The Examiner has not rejected the claims on the basis of lack of utility, and Applicants submit that the stated utility is completely believable given the data in the specification.

The Examiner further goes on to discuss the mechanism of inducing the protective response (page 4, line 12, to page 5, line 1). Applicants note in particular the remark that:

> "Still further, there is no teaching as to what antigens of backbone are being expressed and whether or not the immune response is directed against structural proteins or non-structural proteins."

Applicants submit that these remarks reflect an error in the rejection. The Examiner is discussing a hypothetical mechanism of action of the recombinant herpesvirus when inoculated into the avian host. Applicants assert that the mechanism of action is **irrelevant** with regard to how to make or use the invention of claim 4. Applicants note in this regard MPEP 2164.08, which discusses the basic principle that: "All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim

is enabled." The mechanism of action, and what antigens are produced, are **not recited in the claims** and knowledge of these is not needed to practice the claimed invention.

The Examiner addresses this point in his arguments in the final Office action on page 6, lines 9-13, stating:

> "... [applicants'] assertion that mechanisms of action is not an issue is respectfully noted, however, if the claimed invention is directed to a **certain mechanism of action, such as induction of protection**, then the specification should provide how one can make and use the invention absent undue experimentation as was clearly previously articulated under the 112, 1st paragraph." (emphasis added)

Applicants respectfully submit that the Examiner has misunderstood Applicants' arguments regarding mechanism of action, and that the Examiner's remarks represent an error in the rejection. "Induction of protection" is **not** a mechanism of action. It is a result of carrying out the method, and is the utility recited in the preamble of claims 4 and 5. Applicants have clearly asserted that this utility exists when the method as recited in the claims is carried out. The Examiner has not rejected the claims on the basis of lack of utility, and Applicants assert that this utility is believable. The Examiner does not state how the specification has failed to teach how to carry out the invention of claim 4 or 5.

Finally, on page 6, line 13, of the final Office action, the Examiner states:

> "... if applicants are requesting for broad protection, then they should provide adequate teaching so others would not be forced into undue experimentation. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim."

In response, Applicants submit that the Examiner here states that the *Wands* factors have been considered, yet the Examiner does not actually analyze these factors. On the other hand, Applicants have above carefully reviewed:

1) specifically what experimentation (thereby discussing the quantity of experimentation) is needed to practice the invention, arguing that only standard recombinant virus techniques need be practiced;

2) The issue of unpredictability, showing that the Examiner's citation of a portion of the specification as showing unpredictability did not, in fact, illustrate unpredictability and was not commensurate in scope with the present claims. Applicants have argued that unpredictability is not an issue since the methods taught in the specification for carrying out the invention indicate specifically what to do and are based on methods known in the art, and moreover, working examples are presented;

3) the issue of the breadth of the claims, being careful to discuss enablement commensurate with the scope of the claims.

Applicants therefore believe that there is no basis for concluding that "undue experimentation" is necessary to carry out the invention as claimed.

Applicants therefore assert that claims 1-6 are fully enabled by the specification, and therefore request withdrawal of the rejection of claim groups I, II and III under 35 U.S.C. 112, first paragraph.

In the event this paper is not timely filed, appellant hereby petitions for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 01-2340, along with any other additional fees which may be required with respect to this paper.

Respectfully submitted,

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Enclosures: Appendix

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IX. APPENDIX–CLAIMS INVOLVED IN THE APPEAL

1. (Previously Presented): A recombinant herpesvirus of turkeys harboring an F protein gene of Newcastle disease virus under the control of a promoter of which sequence is shown in SEQ No. 1;

wherein said recombinant herpesvirus of turkeys does not comprise an HN gene.

2. (Previously Presented): A recombinant herpesvirus of turkeys as in claim 1 wherein the promoter and F protein gene are inserted into a noncoding, inter-ORF region of the backbone virus genome.

3. (Original): A recombinant herpesvirus of turkeys as in claim 2 wherein the said noncoding region is that located between UL45 and UL46 of the herpesvirus genome.

4. (Original): A method of inducing protective immunity in an avian host against avian herpesvirus and Newcastle disease virus, which method comprises inoculating the avian host with the recombinant herpesvirus of turkeys as in claim 1, 2 or 3.

5. (Original): A method of inducing protective immunity in an avian host as in claim 4 wherein a recombinant herpesvirus of turkeys is administered to the avian host by subcutaneous or in ovo route.

6. (Original): A poultry vaccine comprising a recombinant herpesvirus of turkeys as in claim 1, 2 or 3.